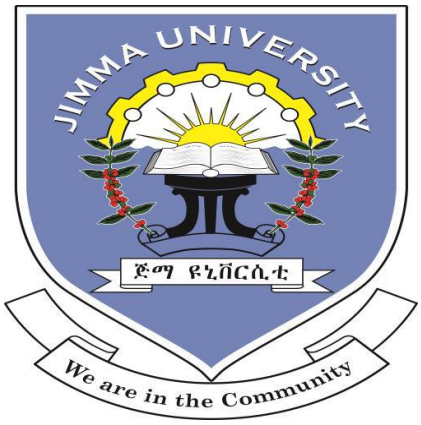
IMPACT OF COVID-19 PANDEMIC ON THE MANAGEMENT OF TUBERCULOSIS AT SHASHAMANNE COMPREHENSIVE AND SPECIALIZED HOSPITAL, SOUTH ETHIOPIA, RETROSPECTIVE COMPARATIVE CROSS SECTIONAL STUDY



BY: LENCHO BATI (B.PHARM)

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ABSTRACT

Background: Following COVID-19 pandemic, tuberculosis has become one of the killer infectious diseases in the globe. During the era of COVID-19, the notification and treatment outcomes of TB were negatively impacted. On other hand, measures taken to control COVID-19 pandemic creates such multidisciplinary disruptions in the management of TB. Early detection of tuberculosis cases and ensuring successful treatment outcomes decreases the burden of TB.

Objective: To assess the impact of COVID-19 pandemic on the management of TB during the era of COVID-19 period.

Methods: A retrospective, comparative cross-sectional study was conducted among 339 TB patients who started TB treatment at Shashamanne comprehensive specialized hospital from August 10, 2018 - October 10, 2021. The study was conducted among extrapulmonary, presumptive and bacteriologically confirmed PTB patients who started anti-TB drugs during the study period and who fulfilled inclusion criteria. The data was entered by Epi-Data version 4.6.1 and analyzed by SPSS version 25. Baseline difference of study variables between the two periods was checked by chi square or fisher's exact test.

Results: A total of 339 study participants were included in the study. Overall TB case reduction was seen among new TB patients who were notified and started treatment during the era of COVID-19 (n =153, 45.1%) compared to the pre- COVID-19 period (n=186, 54.9%). Residence (p=0.014), types of TB (p=0.000), nutritional status (p=0.017), missed doses (p=0.013) and types of laboratory test used (p=0.000) were associated with a baseline difference in TB notification between the pre and era of COVID-19. The treatment outcomes between pre and era of COVID-19 were not significantly different (p=0.058). However, unsuccessful treatment outcome was slightly increased to 5 (3.3%) during the era of COVID-19.

Conclusion and Recommendation: The COVID-19 pandemic had negatively impacted the notification of tuberculosis. Therefore, continues programmatic implementation in increasing notification through active TB case finding in the community and ongoing follow up to decrease missed doses among those started treatment should be needed.

Key word: COVID-19, Impact, Management, Shashamanne, Tuberculosis

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ABBREVIATIONS AND ACRONMYS

AFB: Acid Fast Bacilli

CDC: Center for Disease Control and Prevention

COVID 19: Corona Virus Disease 19

DOT: Direct Observed Therapy

EPTB: Extra Pulmonary Tuberculosis

MAM: Moderate Acute Malnutrition

MUAC: Middle Upper Arm Circumference

MDR-TB: Multi Drug Resistant Tuberculosis

NTLCP: National Tuberculosis and Leprosy Control Program

PHF: Public Health Facility

PPM: Public Private Mix

PTB: Pulmonary Tuberculosis

RH: Rifampin, Isoniazid

RHE: Rifampicin, Isoniazid and Ethambutol

RHPE: Rifampicin, Isoniazid, pyrazinamide and Ethambutol

SAM: Severe Acute Malnutrition

SARS-COV-2: Severe Acute Respiratory Syndrome Corona Virus 2

SERH: Streptomycin, Ethambutol, Rifampicin and Isoniazid

SPSS: Statistical Package for Social Science

TB: Tuberculosis

UN-SDG: United Nation Sustainable Development Goal

WHO: World Health Organization

1. INTRODUCTION

1.1. Background

Tuberculosis (TB) refers to a silent, curable, air-borne disease of the lungs and other organs (1). It is caused by bacillus *Mycobacterium tuberculosis* which is confirmed in 1883 (2). Their mode of transmission through an air enables it to affect all ages and both sexes with more cases observed in adults and males respectively (3). This estimated to one fourth of the world population who has an asymptomatic latent tuberculosis infection (LTBI) on early stage (4). Besides, 5-10% of cases of LTBI are changed into rapidly progressive active cases which accounts for high transmission and drug resistant tuberculosis disease in a context of the poor treatment approach (5-8).

The disease is commonly responsible to cause high morbidity and mortality in different countries of the world including both developed and developing countries. It becomes the second leading infectious killer following the coronavirus disease (COVID-19) in the world with the case fatality rate (CFR) of 14%, of which about 95% of death are in developing countries (8).

Since 1993, TB has been registered as a health emergency (9) and a number of countries are beginning to control it through the adoption of prevention strategies by the World Health Organization (WHO) and the united nation organization for sustainable development goals (UN-SDG). The aim is to reduce deaths from tuberculosis by 95%, cases of incidental tuberculosis by 90% and the catastrophic costs of the disease by 0% by 2035 (8). Achieving of the goal requires the early detection of tuberculosis contacts in collaboration with health workers and the government, early diagnosis, the use of rapid diagnostic technologies, providing effective preventive and first-line drugs for intensive and continuous phase treatment, ensuring patient adherence and monitoring of treatment through close follow up in reducing the incidence of multidrug-resistant tuberculosis (MDR-TB) and for the success of treatment outcomes (3, 8, 10).

Therefore, TB early notification and treatment are used as indices by WHO to control the incidence of TB and mortality worldwide (11). After the application of WHO standard goal between 1980 and 2019, more than 172 million patients received treatment worldwide(12). In 2018, Successful treatment outcomes reported by WHO were 85% for new cases of tuberculosis, 76% for relapses and 57% for TB-HIV positive patients worldwide (8).

Starting from January 2020, the newly emerging COVID-19 pandemic overwhelmed a control of communicable disease including TB (13). COVID-19 pandemic is a deadly airborne viral infection caused by a virus type called Severe Acute Respiratory Syndrome Corona Virus 2 (SARS-CoV-2) that was observed in China, by December 2019 (14). It later spread rapidly around the world and is declared pandemic by the WHO on 11 March 2020 due to its disastrous effect (10, 15, 16).

Worldwide, the number of patients who become positive for the virus were approximately 603, 705,846 with 6,481,145 deaths as of 25 August, 2022 (17). Among African countries; South Africa, Morocco, Tunisia, Egypt, Libia and Ethiopia are the most affected countries respectively (17, 18). In Ethiopia, the first person is identified with virus on 13, March 2020 and state of the emergency measures lunched on 10 April, 2020 (19). Because the country had busiest international airline hubs among 13 African countries which make the country to have direct contact with other high burden countries in the world, the number of cases starts to increase gradually. In the same period with world prevalence of COVID-19 pandemic written above, there were 493, 076 detected cases and 7571 deaths in Ethiopia (17, 20).

1.2. Statement of the problem

Tuberculosis is the world's deadliest infectious disease, with major impacts were during the era of COVID-19 pandemic (21, 22). In 2019, 7.1 million new cases of TB were accounted for more than 4000 and 1.4 million deaths per day and year respectively (4, 23-25). The majority of cases were in India (26%), Indonesia (8.5%) and China (8.4%)(24). In Africa, where 25% of the world's TB cases are present, the notification and treatment of TB are more problematic (24, 26). In addition, it costs more than $6.5 billion per year at a time when income loss exceeds $220 billion in developing countries (8, 27). Ethiopia is among the 30 countries with a high morbidity of TB coupled with poor health care infrastructures. The report showed that about 111,039 new TB cases were seen in 2019 and mortality form the disease is in the top ten and fourth in the world and Africa respectively since 2020 (3, 28).

The shake out of the SARS-CoV-2 virus further impacts management of TB and lead to a reduction in TB new cases to 5.8 million, bringing the total deaths over 1.5 million which was back to the level in 2012(29). The treatment coverage in 2020 were also affected that, it was 50% down from 72% in 2019. Even, an overall reduction in TB mortality from 2015 to 2019 was only 9%, far short of the WHO target of reducing deaths in 35% by 2020 (4, 8, 30). Countries with a high burden of TB have been more impacted and without further action, the fight against TB could be halted and economic losses of $17.5 trillion will be occur worldwide (8, 24).

The impact was increased in the globe and make all members of WHO countries to take different measures used to control the pandemic (31). During the application of these pandemic protection measures, reduction in TB notification were recorded in countries like India where notification was decline by 75% in three weeks (32), 47.8% in Shanghai (33), 43% weekly in Uganda (34) and 34% in Nigeria (35). In addition to these, there were 33% reduction of notification and diagnosis in South Africa (36), 33% in Japan (37), 24% in South Korea (38) as well as 20% in Taiwan (39) at beginning of 2020, compared to other previous years (40). Only one research done on TB notification in Ethiopia showed a 69% reduction of new cases of TB notification in 10 sub cities of Addis Ababa (41). The Study conducted in China and Zimbabwe reported that the successful treatment outcome of TB was decreased from 90.7% to 81.1% and 80.9% to 69.3% respectively (42, 43) (44). However, in Sierra Leone, treatment success was increased oppositely from 46.7%

in 2019 to 55.6% in 2020 (45) and in Kenya, a study showed that treatment success was increased to 67% during 1st six months of COVID-19 pandemic (46).

The major setbacks is linked to the emergency measures taken to control the COVID-19 pandemic, which limits patient follow up, produces stress, fear and economic burdens related to food insecurity as well as cashes among the population (29). These increase the numbers of missed cases in a community which estimate to decrease TB cases visited health facility by 25-50% during the first 3 months of the virus, resulting in a 190,000 (13%) increase in mortality rates, bringing the total numbers of death to 1.66 million in 2020 (47-56).

In addition to the pandemic, factors such as poor treatment outcomes, under nutrition, overcrowding, poor healthcare infrastructure, smoking, catastrophic cost and comorbidity likes human immuno deficiency virus (HIV) infection, diabetes mellitus (DM) and chronic kidney disease (CKD) increases burden of TB disease (51, 57, 58).

Tuberculosis needs immediate action to come up with WHO and UN-SDG strategies in reducing poor treatment outcomes and mortality at this stage where there are persistent gaps in notification and treatment outcomes. This can only be done by aggressive early diagnosis, providing appropriate treatment and monitoring of patients to know treatment outcomes status and factors that influence treatment in general besides preventing the COVID-19 pandemic (59).

The above study (41, 42, 44-46) indicated, the impact of the COVID-19 pandemic on the TB case notification was high as reduction of TB cases varied from 20%- 75% and the treatment outcomes were controversial in the world including Africa and in Ethiopia, there is no published data on the impact of the COVID-19 pandemic on the management of TB concerning notification and treatment outcomes, particularly, in Shashamanne comprehensive specialized hospital. Hence, the aim of the study is to assess the impact of COVID-19 pandemic on the management of TB in terms of notification and treatment outcomes during the era of COVID-19 as compared with the pre COVID-19 period among patient with TB at the Shashamanne comprehensive specialized hospital.

1.3. Significance of the study

Measures taken to control the spread of the virus might impact the TB notification and treatment outcomes in the community of West Arsi zone. However, the impact of COVID-19 pandemic on the management of TB is not clearly known in Shashamanne comprehensive specialized hospital. To manage the risk of transmission and mortality of TB in the whole community during the era of the pandemic, study on the impact of COVID-19 pandemic on the management of tuberculosis in this study setting is paramount. This helps the hospital to realize the gap between pre and era of COVID-19 which enable them to promote the proper management of TB through enhancing active case finding and increasing successful treatment outcomes.

Similarly, this study paper will provide additional information for other concerned governmental and non-governmental organization working in the area of tuberculosis prevention center. It also used as additional sources for further similar studies. Finally, the study is helpful for the planners, managers and health workers in the planning and implementation of effective management of TB during such pandemic in Shashamanne comprehensive specialized hospital, Ethiopia.

2. LITERATURE REVIEW

2.1. Effect of COVID-19 pandemic on tuberculosis notification and treatment outcomes

During the COVID-19 pandemic both notification and treatment outcomes of TB were affected based on different studies in the world. A retrospective, cross-sectional study was performed on 5470 patients from 2017-2020 in the Ningxai Hui region in Northwest China. The study found that, overall TB notification was reduced by 28% in the era of COVID-19 compared to pre COVID-19 period (2017-2019). Unsuccessful treatment outcomes were increased from 407 (9.3%) in the pre COVID-19 to 119 (11.1%) in the era of COVID-19 which was increased by 1.8%. In addition, positive sputum smear test results were increased from 36.5% during the pre COVID-19 period to 50.2% in the era of COVID-19 (43).

A similar cross-sectional study done in Wuhan, China showed that the number of confirmed TB cases during the period without COVID-19 pandemic measures (November 3, 2020- January 24, 2020), lockdown period (January 25- April 8, 2020) and reopen, regular period (April 8, 2020-May 8, 2020) were 53.2%, 51.3% and 50.8% respectively which showed lockdown period due to the COVID-19 pandemic was a significant factor for reduction in TB notification. COVID-19 pandemic also affects sputum examination of patients who finished their DOTS after 2 months which decreased from 68.8% to 60.2%. After full treatment, sputum examination within one week also decreased from 54.6% to 46.4%. according to this study, the number of patients notified with TB were decreased from 379,066 during 2019 (pre COVID-19) to 285,934 in 2020 (era of COVID-19) with reduction difference of 93,132(14%) (42).

A multicenter cohort study conducted in Korea compared 516 patients in March- November 2020 period (era of COVID-19) to 3453 patients between January 2016-February 2020 (pre COVID-19 period). The finding illustrated that the COVID-19 pandemic significantly accounted for a reduction in TB notification by 17%. There was a significant difference in TB notification based on age of patients in which the older age mean was more notified (mean age, 60.2 vs. 56.6 years) during the era of COVID-19. In addition, younger age were significantly fewer as compared with the pre COVID-19 (17.8% in 2020 vs 23.5% in 2019) (60).

Another retrospective cohort study conducted nationally in Korea included all PTB patients which compared the 1st and 2nd quarter of 2020 (era of COVID-19) with 3rd and 4th quarter of 2019 (pre COVID-19) period. It showed that the PTB were decreased from 6066 patients in pre COVID-19 to 4893 in the era of COVID-19 with 1173(10.7%) reduction difference. However, sputum smear test coverage was not significantly different between the two periods. Treatment success among smear positive PTB patients were significantly decreased from 90.6% in pre COVID-19 to 84.1% in the era of COVID-19 with reduction difference of 70(6.5%). Even though the researchers were only discussing about the successful outcomes, unsuccessful outcomes were increased from 109(9.4%) in pre COVID-19 to 186(15.9%) in the era of COVID-19 period. the Lost follow up were decreased from 30(2.6%) to 24(2.1%). But, it was not significant (61).

The retrospective cohort study done in Italy that compared 65 patients linked to TB clinic during the study period (1 March - 30 April 2020) to 76 patients in the control period (1 March – 30 April 2019) indicated that the COVID-19 pandemic significantly accounts for 3(4.6%) deaths as compared to no death in the control period. The pandemic was also significant that new case notification was reduced from 15(19.7%) in the control period to 6(9.2%) in the study period. Lost to follow up was increased from 2.6% to 10.8%. however, socio-demographic data were non-significant in the study (62).

A retrospective cohort study conducted in Zimbabwe showed that during the pre COVID-19 (March 2019- February 2020), 1078 new patients were registered to started anti TB medication compared to 715 patients during the era of COVID-19 (March 2020- February 2021) with 33.7% reduction difference. Bacteriological confirmed cases were reduced by 34.5%. According to the study, the reduction was related to stock out of reagent and assign of health workers to COVID-19 centers. In addition, study showed that, being children (<15 years) was responsible for high reduction (71.3%). Beside these, treatment success was reduced from 80.9% to 69.3% in the pre COVID-19 as compared with the era of COVID-19 respectively and responsible to increase unsuccessful treatment outcomes by 11.8% oppositely. Patient not evaluated was increased from 12.2% to 24.5% and TB patient tested for HIV infection reduced from 95.1% to 90.3% which were identified as factors responsible for the reduction in treatment success (44).

A cohort study conducted on TB patients from March 2019 to February 2021 in Malawi showed that as compared with pre COVID-19 (March 2019 - February 2020) presumptive TB notification

reduced by 45.7% and laboratory confirmed EPTB reduced by 25.7% during the era of COVID-19 (March 2020 - February 2021). In this study, being children (<15 years) and females were responsible for reduction by 67.8% and 52% respectively. Treatment success was reduced from 96.1% to 96% in the era before COVID-19 as compared with the era of COVID-19 respectively with 0.1% increment in unsuccessful treatment outcomes. Death was decreased by 0.6%, patient not evaluated was increased from 0.9% to 1.2%, bacteriologically confirmed PTB reduced by 2.6% (63).

A cross sectional comparative study done in a university teaching hospital in Nigeria showed, there were 200 presumptive cases between April to May 2019. However, in 2020, only 20 clinically diagnosed cases were registered from April to May 2020. This indicated, only 7% of the number of presumptive cases detected in 2020. It was low as compared with the cases of 46% over the same period in 2019. In the study, 2 cases of Lost to follow up seen between April to May 2020 but no death was recorded. The researcher identified that the reduction could be as a result of the lockdown and limit accessibility to the test (35).

A retrospective cohort study done from January 2019 to September 2020 in Sierra Leone reported that TB case notification was reduced from 2636 patients in the pre COVID-19 (January 2019-March 30, 2020) to 2300 patients during the era of COVID-19 (April 2020- September 2020) which was 12.7% reduction. From this, females were responsible for reduction by 24.9% and the males were reduced by 2.3% as compared with 2019. Notifications from children were reduced by 19.6% while adults were reduced by 12.3%. Newly diagnosis reduced from 89.9% to 87.1% while relapsed cases increased from 10.1% to 12.9%. Among TB-HIV positive notification, case notification increased from 33.6% to 36.8% which was increased by 2%. However, Self-reporting increase by 7.7% and health facility related referrals increase by 46.6%. Treatment success rate increase from 46.7% to 55.6% and pulmonary tuberculosis was also increased from 95.3% to 95.5% as compared with the era before the pandemic (45).

Cohort study was conducted in Kenya from March 2020 to February 2021(era of COVID-19) and compared with the pre COVID-19 (March 2019 to February 2020). In the study, the reduction was greater in children under the age of 15 (by 50.2%) than in adults (27.3%). Again, the numbers of females notified were significantly affected than males (by 35.2% vs 2.6% reduction respectively). The numbers of cases confirmed by bacteriologically, presumptive, EPTB and TB-HIV were

reduced by 32.7%, 22.1%, 23.3%, and 1.7% respectively. During the pandemic death was increased by 0.8 % (4.2% in 2019 vs 5% in 2020). However, during the pandemic, successful treatment outcome was increased (65% in 2019 vs 67% in 2020), lost to follow up reduced by 0.3% and treatment failure was decreased by 0.3% (46).

A retrospective cross-sectional study done in Addis Ababa on the notification of TB by including 212 patients in 10 sub cities indicated that, during the COVID-19 pandemic (quarter two of 2020), patient flow was decreased by 69% as compared to the pre COVID-19 period (quarter one of 2020). Also, during quarter three of 2020 (the era of COVID-19) the decline in patient flow was still 69% compared to the pre COVID-19 period (quarter one of 2020) and the overall decline was 69%. The researcher identify that, the stigma and lockdown period as factors responsible for decrease in notification (41).

2.2. Conceptual Frame Work

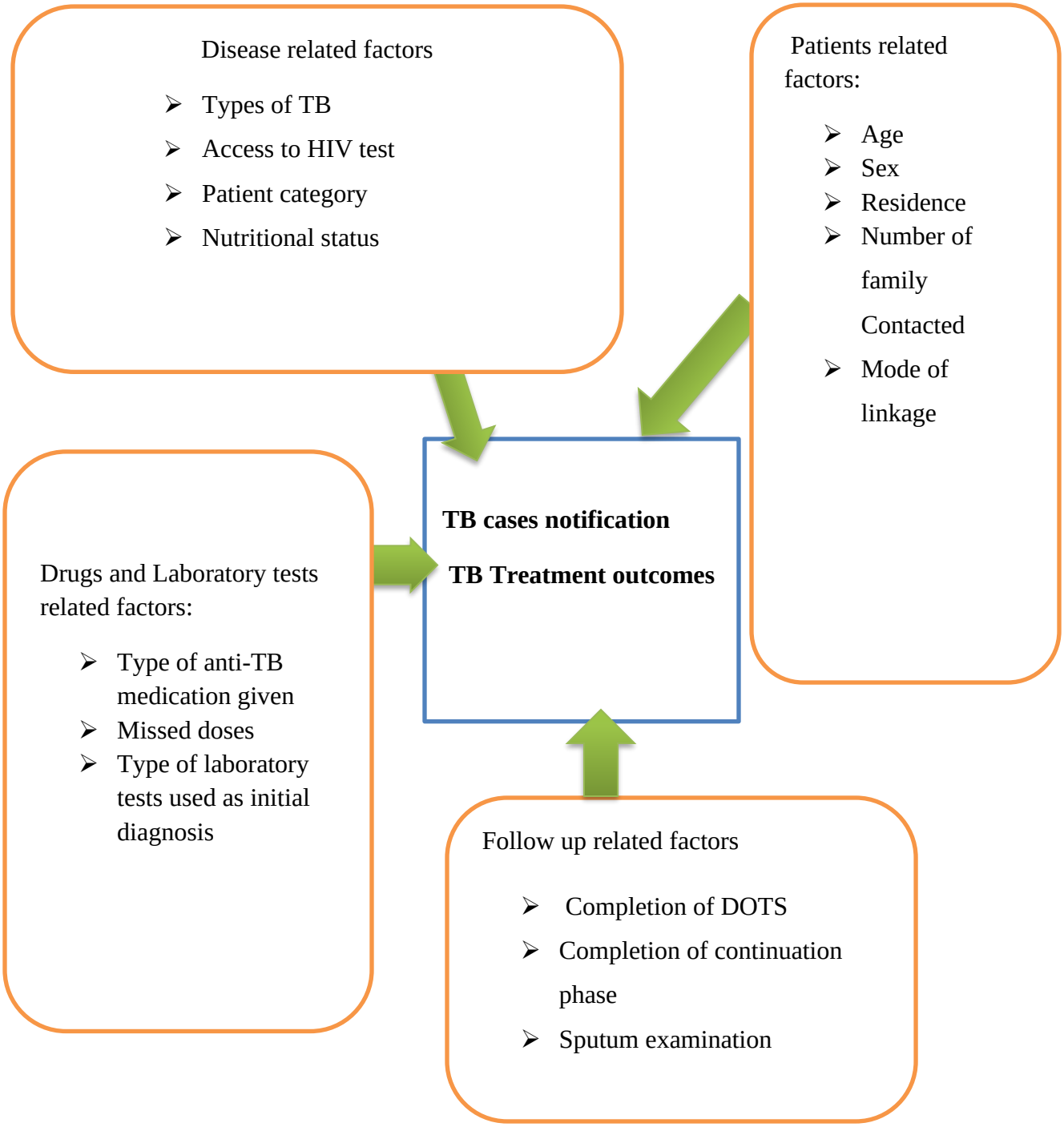

Figure 1: Conceptual frame work for the impact of COVID-19 pandemic on tuberculosis management at Shashamanne comprehensive specialized hospital, South Ethiopia, August 10, 2018- October 10, 2021

3. OBJECTIVES

3.1. General objective

- To assess the impact of COVID-19 pandemic on the management of TB during the era of COVID-19 among TB patients at Shashamanne comprehensive specialized hospital from August 10, 2018 - October 10, 2021

3.2. Specific objectives

- To compare TB case notification among patients started treatment during the pre and era of COVID-19 period at Shashamanne comprehensive specialized hospital from August 10, 2018 - October 10, 2021.
- To compare treatment outcome among patients with TB during the pre and era of COVID-19 period at Shashamanne comprehensive specialized hospital from August 10, 2018 - October 10, 2021.

4. METHODS AND MATERIALS

4.1. Study area and study period

The study was carried out at Shashamanne comprehensive specialized hospital, 240 km away from Addis Ababa, in Southern Ethiopia. It was one of the unique referral facilities of the zone, serving approximately 2.1 million people in the Western Arsi zone. The study was conducted from August 10, 2018 - October 10, 2021 to assess the impact of COVID-19 pandemic on the management of TB during the era of COVID-19 compared to the pre COVID-19 period in patients with TB at comprehensive specialized hospital in Shashamanne city. Period from August 10, 2018 – March 12, 2020 was considered as the pre COVID-19 period while March 13, 2020 – October 10, 2021 was considered as the era of COVID-19.

4.2. Study Design

A retrospective, comparative cross-sectional study was performed to assess the impact of COVID-19 pandemic on the management of TB among patients followed at Shashamanne comprehensive specialized hospital during the pre and era of COVID-19 period

4.3. Population

4.3.1. Source population

- All patients who were registered for diagnosis and treatment of tuberculosis at Shashamanne comprehensive specialized hospital

4.3.2. Study population

- Presumptive, bacteriologically confirmed PTB and EPTB patients started anti-TB drugs and who fulfilled the inclusion criteria at Shashamanne comprehensive specialized hospital from August 10, 2018 – October 10, 2021

4.4. Inclusion and Exclusion Criteria

4.4.1. Inclusion Criteria

- TB patient charts for all age groups who have begun anti-TB medication.

4.4.2. Exclusion Criteria

- Incomplete data record
- MDR TB, Extended MDR TB record
- Transferred out

4.5. Sample size and sampling technique

4.5.1. Sample size

All presumptive PTB, laboratory confirmed PTB and EPTB patients fulfilled inclusion criteria were retrieved from records of patient registration during the study period and included for the study

4.5.2. Sampling technique

Consecutive sampling technique in which every patient charts meeting the criteria of inclusion was selected

4.6. Variables

4.6.1. Dependent variables

- Tuberculosis New cases notification
- Tuberculosis Treatment outcomes

4.6.2. Independent variables

- Patients related factors:
  - Age
  - Sex
  - Residence
  - Numbers of family Contact
  - Mode of linkage
- Clinical characteristics related factors:
  - Types of TB
  - Patient category

- Access to HIV test
- Nutritional status at start of medication

❖ Drugs and Laboratory tests related factors:

- Type of anti-TB medication given
- Missed doses
- tests used as initial diagnosis

❖ Follow up related factors:

- Completion of intensive phase
- Completion of continuation phase
- Sputum examination during treatment

4.7. Data collection and procedure

To start data collection, a unique TB code was obtained first from dispensary registry books at OPD TB clinic to easily get patient charts from record office. Patients' charts collected together and taken to TB clinic. Demographics, clinical characteristics, treatment approach, follow up status and treatment outcomes of TB patients started treatment at TB clinic were obtained from both TB registration book and patient charts. Then data were filled on prepared structured questionnaire by two trained data collectors selected from department of pharmacy and nursing who were worked at Shashamanne comprehensive specialized hospital.

Outcome variables such as TB case notification measures in terms of numbers of new cases started treatment and treatment outcomes status, measured in terms of treatment success and unsuccessful treatment outcome. The Ethiopian national TB and leprosy control program guidelines updated during 2019 were used to validate outcomes variables through the study (3).

4.8. Quality assurance

The questionnaire was developed by English language. The completeness of each questionnaire was checked before data collection. Prior to start actual data collection, the data collection questionnaire was pre-tested in 16 charts of study participants by principal investigator in order to check for the presence of full required variables of the study as per the objectives. On this basis, the amendments and arrangements of some variables were made on the data collection

questionnaire. The principal investigator was trained data collectors to the procedure of data collection for one day. During data collection period, the principal investigator was supervised & verified the readability and completeness of filled questionaries whether it was enough to ensure the quality of data needed.

4.9. Data analysis

After data collection, data was organized and arranged as patient from the pre COVID-19 period and era of COVID-19 separately. Then, data was entered into Epi-data version 4.6.1 for cleaning and transferred to SPSS version 25 for further analysis. Notification and treatment outcomes related factors were compared between patient's data collected in the era of COVID-19 with the pre COVID-19 period by calculating percent difference between them using formula of (pre COVID-19 frequency - era of COVID-19 frequency)/total study participants) x100. Positive change showed increase in magnitude from baseline (pre COVID-19) and negative change indicates decrease in magnitude from pre COVID-19 period. Pearson's chi square or fisher's exact test was used to check the baseline difference of the study variables. A P-value less than 0.05 were considered as variables used to indicate baseline difference between the two periods. The result was presented in terms of percentage, frequency tables, cross tabulation, graphs and discussed with previous findings. Finally, possible recommendation was made based on the findings of the study.

4.10. Ethical consideration

Ethical clearance issued with reference number JUIRB012/14 were obtained from an ethical review committee of Jimma University before starting data collection. Legal support letter from institute of health, School of pharmacy, Jimma University was given to Shashamanne comprehensive specialized hospital to obtain permission of data collection. Objective of the study was clarified to the chief executive officer and medical director of the hospital for cooperation. The information obtained was kept confidential.

4.11. Dissemination of the results

The findings of this research will be presented to the school of pharmacy, Institute of health, Jimma University and other concerned bodies. Then, it will be reported to Shashamanne comprehensive

specialized hospital. Finally, an effort will be made to present in various seminars, workshops and published on international reputable Journals.

4.12. Operational and term definitions

Based on the standard definitions of the National Tuberculosis and Leprosy Control Program (NTLCP), 2018 guideline adopted from Ethiopian Ministry of Health, the following definitions will be used (3).

Bacteriologically confirmed TB case: A patient who has presented with at least one positive biological specimen for mycobacterial tuberculosis by microscopic smear, Xpert MTB/RIF or culture.

Category of patient: A patient who were registered as new, relapse or transfer in at start of their anti-TB medication

Completed Treatment: A patient with a record of completed treatment and no record with failure, but, no sputum or culture results in the last month of treatment and on at least on the previous occasion were negative, either because not tested or results are unavailable.

Died: A patient who had been died during their course of TB treatment.

Extra-pulmonary tuberculosis (EPTB): A patient who has received a bacteriological or clinical diagnosis of tuberculosis cases involving organs other than the lungs.

Lost to Follow Up: A patient on tuberculosis treatment for a minimum of 1 month and who interrupted his/her treatment for 2 months or more.

Missed doses: If the patients' losses the medication for a minimum of single doses from their daily intake either during DOTS or continuation phase

Moderate Acute Malnutrition: Those TB patients' MUAC measurement were 11.5-12.5cm, 13.5-14.5cm and 16-18.5cm for age 6-59 months, 5-9 years and 10-15 years respectively. For adults, if BMI were 16-18.5kg/m^2. Those greater than these ranges are considered as normal. However, if TB patients' MUAC measurement were <11.5cm, <13.5cm and <16cm for age 6-59

months, 5-9 years and 10-15 years respectively and adults BMI were <16kg/m^2, they considered as SAM (64).

New case (N): A patient who has never been treated for TB or who has already been on TB treatment for less than four weeks.

Notification: Number of new cases identified for TB treatment in a given time

Presumptive Tuberculosis case: Any person with symptoms and/or signs suggestive of tuberculosis, in particular cough of two weeks or more duration

Pulmonary tuberculosis (PTB): patient with any bacteriologically confirmed or clinically diagnosed case of TB involving the lungs

Relapse (R). A patient declared cured or treatment was completed of any form of TB in the past but who visits back to the health service and is again positive for AFB smear positive or culture

Smear Negative Pulmonary TB: This is a patient with symptoms indicative of TB with a minimum of two samples of microscopic negative expectoration for AFB and with chest radiographic abnormalities compatible with pulmonary active TB (including abnormal interstitial or miliar images) or a patient with two sets of at minimum two sputum samples taken at least 15 days apart and AFB test is negative by microscopy and radiographic abnormalities compatible with pulmonary TB and lack of clinical improvement to a Week of broad spectrum antibiotic.

Smear Positive Pulmonary TB: A patient with minimum of two sputum specimens were positive for acid-fast bacilli (AFB) by microscopy or only one sputum specimen was positive for AFB by microscopy and radiographic chest abnormalities were evident for active pulmonary TB.

Successful Treatment outcomes: The number of cured plus treatment completed patients.

Transfer in: A patient who is transferred to continue treatment at a given reporting unit after starting treatment in another reporting unit.

Transferred Out: Cases transferred out to another health facility.

Unsuccessful Treatment outcomes: Include died, failure, moved to MDR-TB and lost to follow-up

5. RESULT

This study included a total of 339 new TB patients charts who started treatment from August 10, 2018 to October 10, 2021 at Shashamanne comprehensive specialized hospital, South Ethiopia.

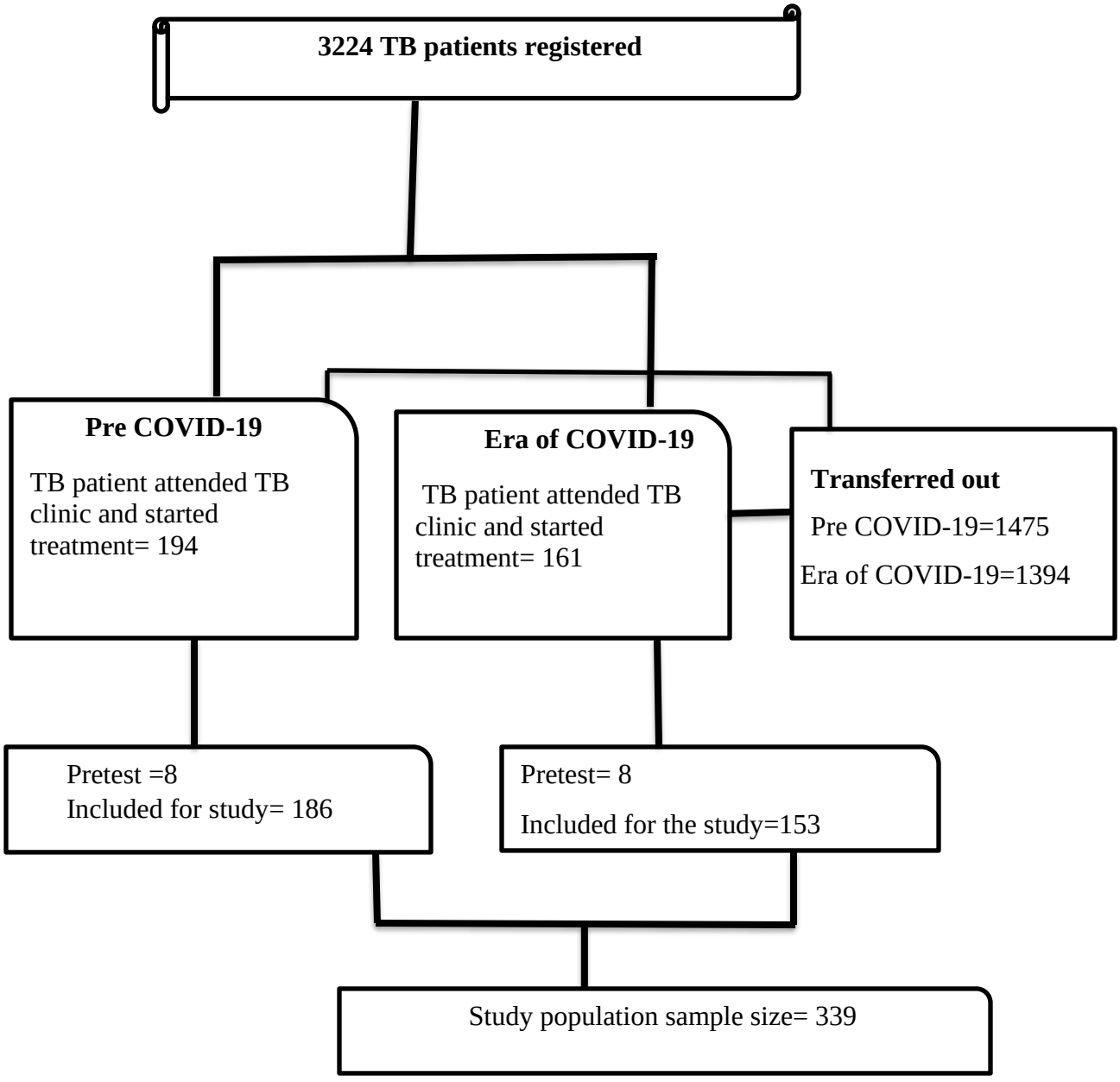

Figure 2: Flow charts for TB patient's enrollment for the assessment of the impact of COVID-19 pandemic on the management of TB at Shashamanne comprehensive specialized hospital, South Ethiopia, August 10, 2018- October 10, 2021

5.1. Socio demographic characteristics of study participants

The majority of study participants who were enrolled for the study were male during the pre COVID-19 period (n= 100, 53.8%) and 81 (52.9%) of males were notified during the era of COVID-19. During the era of COVID-19, the mean age of the study participants who were notified was lower when compared to the pre COVID-19 period (29.56 vs. 33.45 years).

Overall TB case reduction was seen in new TB patients who were notified and started treatment during the era of COVID-19 (n =153, 45.1%) when compared to the pre- COVID-19 period (n=186, 54.9%) showing 33 (9.7%) reduction difference. Both males and females experienced the reduction, with a difference in reduction of 5.6% and 4.1% respectively (p = 0.880). In addition, patients older than or equal to 15 years old were less notified and start treatment during the era of COVID-19 compared to the patient during the pre COVID-19 period (n=126, 82.4% vs. n=164, 88.2%), which accounts for the 11.2% reduction difference (p=0.129). Moreover, when compared with residents of the pre COVID-19 period, patients coming from rural areas experienced a greater decrease in TB notification during the era of COVID-19 (12.1% reduction difference, p=0.014) (see table 1 below).

Table 1: Socio demographic characteristics of TB patients attending TB clinic at Shashamanne comprehensive specialized hospital during pre and era of COVID-19. August 10, 2018- October 2021

Characteristics		Duration of TB notification		Total n=339	Percent difference	p-value
		Pre COVID-19	Era of COVID-19			
Numbers of TB cases assessed		186(54.6%)	153(45.1%)	339(100%)	-9.7%	
Sex						0.880
	Male	100(53.8%)	81(52.9%)	181(53.4%)	-5.6%	
	Female	86(46.2%)	72(47.1%)	158(46.6%)	-4.1%	
Age						0.129
	< 15	22(11.8%)	27(17.6%)	49(14.5%)	+1.5%	
	≥15	164(88.2%)	126(82.4%)	290(85.5%)	-11.2%	
Residence						**0.014**
	Urban	70(37.6%)	78(51.0%)	148(43.7%)	+2.4%	
	Rural	116(62.4%)	75(49.0%)	191(56.3%)	-12.1%	
Mode of linkage						0.127
	PHF	174(93.5%)	136(88.9%)	310(91.4%)	-11.2%	
	PPM	12(6.5%)	17(11.1%)	29(8.6%)	+1.5%	
Numbers of family contacted						0.602
	< 2	43(23.1%)	30(19.6%)	73(21.5%)	-3.8%	
	2-4	77(41.4%)	71(46.4%)	148(43.7%)	-1.8%	
	≥ 5	66(35.5%)	52(34.0%)	118(34.8%)	-4.1%	

PHF: Referral from/with in public health facility to TB clinic; **PPM**: Referral from private public mix; +: increase in percent difference of tuberculosis patients between pre and era of COVID-19; -: decrease in percent difference of tuberculosis patients between pre and era of COVID-19; percent difference: (frequency difference between pre and era of covid-19/total study participants) x100

The number of patients who were notified and started treatment during the 1st five months of the era of COVID-19 (March 13 - July 31, 2020), were reduced to 36 (23.5%) compared to 50 (26.9%) patients notified in the same season (March 13- July 30, 2019) in the pre COVID-19 (4.1% reduction difference). However, there was an increase in numbers of notified patients to 46 (30.1%) when compared with similar months in 2021 during the era of COVID-19 (**Figure 3**).

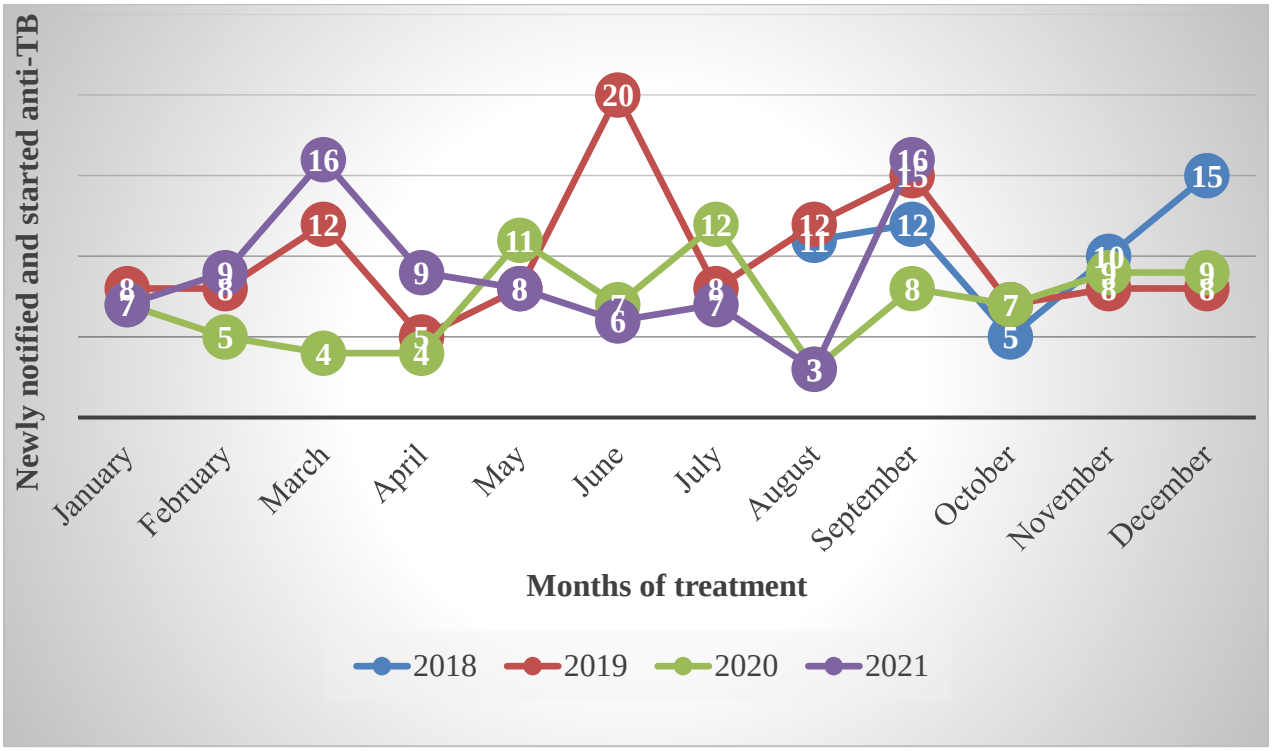

Figure 3: Trends in monthly cases among patients with TB treatment notification during pre and era of COVID-19 at Shashamanne comprehensive specialized hospital, South Ethiopia, August 10, 2018- October 10, 2021

5.2. Clinical characteristics of study participants

Bacteriologically confirmed PTB patients experienced 27(8%) increase in notification during the era of COVID-19 compared to the pre COVID-19 period (p=0.000). However, presumptive PTB patients who were notified and started treatment within the era of COVID-19 was reduced compared to those in the pre COVID-19 period with 16.5% reduction difference (p=0.000). Data for the category of TB patients revealed that, during the era of COVID-19 the patient recorded

with relapse was increased when compared to patients during the pre COVID-19 period (n=15,9.8% vs. n=9, 4.8% with increment difference 1.8%) (p=0.198). Compared to patient notified during the pre COVID-19 period, there was 5(1.5%) and 4(1.2%) more increase in SAM and MAM, among TB notified patients during the era of COVID-19 respectively (p=0.017) (see table 2 below).

Table 2: Clinical characteristics of TB patients attending TB clinic during pre and era of COVID-19 at Shashamanne comprehensive specialized hospital. August 10, 2018- October 10, 2021

Characteristics	Duration of TB notification		Total n=339	Percent difference	p- value
	Pre COVID-19 period	Era of COVID-19			
Types of TB identified					**0.000**
Presumptive PTB	117(62.9%)	61(39.9%)	178(52.5%)	-16.5%	
Bacteriologically confirmed PTB	34(18.3%)	61(39.9%)	95(28.0%)	+8%	
Extra pulmonary TB	35(18.8%)	31(20.3%)	66(19.5%)	-1.2%	
Patient category					0.198
New	174(93.5%)	135(88.2%)	309(91.2%)	-11.5%	
Relapse	9(4.8%)	15(9.8%)	24(7.1%)	+1.8%	
Transfer in	3(1.6%)	3(2.0%)	6(1.8%)	0%	
HIV status					0.066
Positive	8(4.3%)	5(3.3%)	13(3.8%)	-0.9%	
Negative	138(74.2%)	98(64.1%)	236(69.6%)	-11.8%	
Unknown	40(21.5%)	50(32.7%)	90(26.5%)	+2.9%	

Nutritional status at start of medication				**0.017**
SAM	40(21.5%)	45(29.4%)	85(25.1%)	+1.5%
MAM	39(21.0%)	43(28.1%)	82(24.2%)	+1.2%
Normal	94(50.5%)	62(40.5%)	156(46.0%)	-9.4%
Unknown	13(7.0%)	3(2.0%)	16(4.7%)	-2.9%

HIV: Human immuno deficiency virus; SAM: Severe Acute Malnutrition; MAM: Moderate Acute Malnutrition; unknown: patient when their result is not documented on TB registry book; -: decrease in percent difference of tuberculosis patients between pre and era of COVID-19; +: increase in precent difference of tuberculosis patients between pre and era of COVID-19

5.3. Drugs and laboratory tests of study participants

During the era of COVID-19 pandemic, majority of patients, 109 (71.2%) were notified by Gene expert as initial diagnosis of tuberculosis compared to 58 (31.2%) patients in the pre COVID-19 period which showed 15% increment difference (p=0.000). However, patient notified by sputum microscopy were 13 (8.5%) during the era of COVID-19 when compared to 93 (50%) patients before the pandemic (p=0.000). Moreover, patients during era of COVID-19 who missed their doses while on their anti TB treatment were increased to 7 (4.6%) as compared to 1 (0.5%) in pre COVID-19 period (1.8% increment difference, p=0.013) (see table 3 below).

Table 3: Drug and laboratory tests related factors of TB patients attending TB clinic at Shashamanne comprehensive specialized hospital during pre and era of COVID-19, August 10, 2018- October 10, 2021.

Characteristics		Duration of TB notification		Total n=339	percent Difference	P value
		Pre COVID-19 period	Era of COVID-19			
Laboratory tests used for TB notification						**0.000**
	Sputum microscopy	93(50%)	13(8.5%)	106(31.3%)	-23.5%	
	Gene expert	58(31.2%)	109(71.2%)	167(49.3%)	+15%	
	Culture/FNAC	25(13.4%)	21(13.7%)	46(13.6%)	-1.2%	
	x-ray	10(5.4%)	10(6.5%)	20(5.9%)	0%	
Anti TB medication given						**0.000**
	2RHZE/4RH	174(93.5%)	138(90.2%)	312(92%)	-10.6%	
	2RHZ+E/4RH	12(6.5%)	15(9.8%)	27(8%)	+0.9%	

Missed doses				**0.013**
Yes	1(0.5%)	7(4.6%)	8(2.4%)	+1.8%
No	185(99.5%)	146(95.4%)	331(97.6%)	-11.5%

FNAC: Fine needle Aspiration; RHZE: combination of rifampicin, isoniazid, pyrazinamide and ethambutol for the 1st two months followed by rifampicin and isoniazid for next four months; TB: Tuberculosis; -: decrease in percent difference of tuberculosis patients between pre and era of COVID-19; +: increase in percent difference of tuberculosis patients between pre and era of COVID-19

5.4. Follow up related factors of study participants

The percentage of TB notified patients who had documented with SAM at the end of full treatment was increased from 5 (2.7%) during the pre-COVID-19 to 10 (6.5%) in an era of COVID-19 with 1.5% increment (p=0.080). Among patients notified during the era of COVID-19, 3 (9.7%) EPTB patients did not properly finish their doses during the continuation phase compared to those in the pre COVID-19 period which account to 0.9% increment (p=0.098). Beside this, 2 (1.6%) PTB patients during DOTS schedule, did not properly taken their doses during the era of COVID-19 compared to 1 (0.7%) patient during the pre-COVID -19 period (p=0.588). The numbers of presumptive and bacteriologically identified TB patients who have not properly completed their continuation phase schedule during the era of COVID-19 was increased to 4 (3.3%) compared to 1 (0.7%) in the pre COVID-19 period (p=0.017) (see table 4 below).

Table 4: Follow up related factors of TB patients attending TB clinic at Shashamanne comprehensive specialized hospital during pre and era of COVID-19 period. August 10, 2018- October 10, 2021

Characteristics	Duration of TB notification		Total	Percent difference	P value
	pre COVID-19	Era of COVID-19	n=339		
Tests result at the end of 2nd month of treatment					
Positive	1(0.5%)	0(0%)	1(0.3%)	-0.3%	
Negative	34(18.3%)	59(38.6%)	93(27.4%)	+7.4%	
Not tested	151(81.2%)	94(61.4%)	245(72.3%)	-16.8%	
Tests result at the end of 5th month					**0.000**
Negative	34(18.3%)	54(35.3%)	88(26%)	+5.9%	
Not tested	152(81.7%)	99(64.7%)	251(74%)	-15.6%	
Tests result at the end of full treatment					**0.005**
Negative	34(18.3%)	48(31.4%)	82(24.2%)	+4.1%	
Not tested	152(81.7%)	105(68.6%)	257(75.8%)	-13.8%	
Nutritional status at end of full treatment					**0.080**
SAM	5(2.7%)	10(6.5%)	15(4.4%)	+1.5%	
MAM	40(21.5%)	41(26.8%)	81(23.9%)	+0.3%	

Normal	131(70.4%)	99(64.7%)	230(67.8%)	-9.4%	
Unknown	10(5.4%)	3(2%)	13(3.8%)	-2.1%	
Appointment in continuation phase for EPTB finished properly (n=66)					0.098
Yes	35(100%)	28(90.3%)	63(95.5%)	-2.1%	
No	0(0%)	3(9.7%)	3(4.5%)	+0.9%	
DOTS for presumptive and bacteriological PTB started and finished properly(n=273)					0.588
Yes	150(99.3%)	120(98.4%)	270(98.9%)	-8.8%	
No	1(0.7%)	2(1.6%)	3(1.1%)	+0.3%	
Appointment in continuation phase for presumptive and bacteriological PTB finished (n=273)					
Yes	150(99.3%)	118(96.7%)	268(98.2%)	-9.4%	**0.017**
No	1(0.7%)	4(3.3%)	5(1.8%)	+0.9%	

EPTB: Extrapulmonary tuberculosis; MAM: Moderate acute malnutrition; SAM: Severe acute malnutrition; TB: Tuberculosis; unknown: patients whose their nutrition status were not registered on tuberculosis registry book; -: decrease in percent difference of tuberculosis patients between pre and era of COVID-19; +: increase in percent difference of tuberculosis patients between pre and era of COVID-19

5.5 Treatment outcomes of study participants

In the study participants, 60 (39.2%) TB patients notified were cured during the era of COVID-19, compared to 34 (18.3%) patients in the pre COVID-19 period suggesting 20.9% increase in difference. The proportion of patients who completed treatment were decreased during the era of COVID-19 (n=151, 81.2%) compared to pre COVID-19 period (n=88, 57.5%) with 23.7% reduction difference. This account for the reduction difference of 2.8% in successful treatment outcomes compared with the pre COVID-19 period. On other hand, the proportions of patients died were increased from 1 (0.5%) in the pre COVID-19 to 3 (2%) in an era of COVID-19 period and 2 (1.3%) were lost their treatment during follow up in the era of COVID-19 compared to 0 (0%) in the pre COVID-19 period, which accounted to slight increase in unsuccessful outcome to 5 (3.3%) during the era of COVID-19 compared to the pre COVID-19 period with 2.8% increment difference (see table 5 below).

Table 5: WHO Treatment outcomes of TB patients attending TB clinic at Shashamanne comprehensive specialized hospital during pre and era of COVID-19 period. August 10, 2018-October 10, 2021

Characteristics			Duration of treatment outcome		Percent difference	p-value
			Pre COVID-19	Era of COVID-19		
Treatment outcome	Successful		185(99.5%)	148(96.7%)	-2.8%	**0.058**
		Cured	34(18.3%)	60(39.2%)	+20.9%	
		Completed	151(81.2%)	88(57.5%)	-23.7%	
		lost to follow up	0(0.0%)	2(1.3%)	+1.3%	
		Died	1(0.5%)	3(2%)	+1.5%	
	Unsuccessful		1(0.5%)	5(3.3%)	+2.8%	

6. DISCUSSION

The study assessed the impact of the COVID- 19 pandemic on the notification of new cases of TB to start TB treatment and treatment outcomes at the Shashamanne comprehensive specialized hospital. The study found that TB notification among patients who had begun treatment for the disease were decreased during the era of COVID-19 by 9.7% when compared to same season in the pre COVID-19 period.

With regard to new TB notification to start treatment, the current finding was consistent with the study done in North Italy, where TB notification was reduced by 10.5% (62), Korea 10.7% (61) and Sierra Leone 12.7% (45). In contrast to this finding, higher reduction was recorded from South Korea, where TB notification decreased by 17% (60), Ningxia hui, China 28% (43), Zimbabwe 33.7% (44) and China 14% (42). These might be due to differences in severity of the pandemic and lack of access to health facilities during the pandemic, particularly in China (42, 43), variations in the region's response to the pandemic, decreased services of TB during the pandemic (43), smaller sample size in this study and different study design applied.

In this study, as the overall yearly based reduction in notification of TB was happened during the era of a COVID-19 pandemic, variations between months were also commonly seen when compared to the pre COVID-19 period. During the 1st five months of the pandemic the notified patients who started treatment were more decreased to 36(23.5%). Later five months showed an increment in notification to 46 (30.1%) after emergency measures were partially stopped compared to the pre COVID-19 period, which were consistent with all studies discussed above. This might imply that, there were undetected numbers of missed active TB cases among the community during the 1st five months of the pandemic. The modeling analysis done during early occurrence of pandemic showed that the TB service destruction occurs for few months and it was temporary issues (56). But this study commonly indicates destruction stay yearly and responsible to significant increase in missed doses (p=0.013) among patient taking their anti-TB medication.

Among the sociodemographic characteristics, the impact of residence has been evaluated and it was found that there was association between residency and reduction of TB cases notification (p=0.014) during the era of COVID-19 compared to the pre COVID-19 period. However, other similar studies conducted in different countries of the world did not assess the impact of residence

on the notification of TB (45, 62, 63, 65, 66). According to this study, the national emergency measures implemented to overcome the pandemic and stigma toward the virus (45) might be enabling patient who found in rural areas in order not to visit the health facility. Additionally, because the symptoms of both TB and the COVID-19 disease were similar, patients who experienced them may developed fear whether they were caused by COVID-19 or TB and prefer to stay at home with their families rather than visiting the health facilities (67). This resulted in delay in TB notification and treatment which led to further accumulation of active case of TB in the community (65, 68). This was evidently seen after the later five months of pandemic where new cases increased from 36 (23.5%) in the 1st five months of pandemic to 46 (30.1%) in the next five months.

Although presumptive and extrapulmonary TB decreased by 16.5% and 1.2% respectively, bacteriologically identification was increased by 8% (p=0.000). The study was consistent with the study conducted in Sierra Leone, where bacteriological confirmed cases increased by the difference of 8.1% (45). The finding was lower than the study done in Ningxai Hui, China, 50% (43). The discrepancy might be due to difference in severity of the pandemic, difference in TB program implementation and severity symptoms of TB seen during the pandemic as a result of delay or reduce in notification. The reduction of bacteriologically notification were reported in study from Malawi 2.6% (63), Zimbabwe 34.5% (44) and Kenya 32.7% (46) oppositely. This discrepancy might be related to differences in types of laboratory tests used. In other literature, during the lockdown measures, patient visit to health facility were reduced and later the patients with severe symptoms suggestive of PTB were visiting the facility so that they more considered as smear positive (43) and this was evidently seen in this study. This might indirectly indicate that there were missed active cases in the community with a chance of transmission among family as discussed above.

The use of gene expert was increased by 15% which was similar with study conducted in China 13.5% (43) and the use of modern laboratory was maintained in Serra Lione (45), even though the types of tests used were not specifically studied. However, the identification of TB cases by modern laboratory diagnostic method was affected in Malawi (63), Zimbabwe (44) and Kenya (46). The difference might be described in terms of two ways. First, when compared with the WHO TB standard goal toward control of TB (8), the application of gene expert as initial diagnosis of

TB was less practiced and laboratory operation was not intact compared with this finding. Secondly, in this finding, the patients coming to the facility during the era of COVID-19 were delayed with active TB in the community so that they might had severe illness and enforced the facility to use gene expert to sensitively identify the TB.

In addition, more TB patients were recorded with SAM (n=45, 29.4%) compared to those in the pre COVID-19 period (n= 40, 21.5%) (p=0.017). Despite the fact that, there was little information related to this in the literatures, this might be due to severity of TB, losses of incomes and high prices of foods (69). Moreover, follow up status of the patient during the era of COVID-19 was affected. Particularly, sputum examination after full treatment of anti TB medication significantly affected during the era of COVID-19 period (p= 0.000) although different studies discussed above excluded from their studies. Again, the majority of patients missed their doses (n=4, 3.3%) were found in the continuation phase.

Unlike previous studies (43, 62, 63) which reported high association between TB treatment outcomes and COVID-19 pandemic, current study did not showed association between pre and era of COVID-19 vs. TB treatment outcome (p=0.058). This might be due to smaller cell count of each sub group of unsuccessful outcome variables as well as large number of transferred out patients excluded from this study which might have compromised precision of the finding.

However, study showed a slight increase in unsuccessful treatment outcomes to 5 (3.3%) during the era of COVID-19 with 2.8% increment difference. Similarly, lost to follow up and death were increased from 0% to 1.3% and 0.5% to 2% respectively. The current study was comparable with one done in Ningxai hui, China 1.8% (43). Besides, the finding was higher than study done in Malawi 0.1% (63).the discrepancy might be related with difference in study design used and higher severity of pandemic in our country. However, the finding was lower than study conducted in Zimbabwe 11.8% (44). Again, this study differs with those conducted in Kenya (46) and Sierra Leone (45) which both found an increased in TB successful treatment outcomes. The disparity in treatment outcomes might be due to the difference in an overall adequacy level of TB program implementation and follow up status, the difference in the control measures of pandemic by region, study population, sociodemographic data and difference in sample size.

This study has few limitations which involve comparative cross sectional study design used. Cross sectional study deals with only point prevalence that the study depends only on patient charts.

Besides, this study only analyses the short term impact of the pandemic on the non-resistant TB management approach and did not analyze the long term impact of the COVID-19 pandemic on TB diagnosis and treatment which need to be studied further. Moreover, the study done only in one facility and it did not represent the country as a whole.

7. CONCLUSION AND RECOMMENDATION

7.1 CONCLUSION

The COVID- 19 pandemic negatively impacted TB management during the era of COVID-19. The TB notification among patient started treatment were decreased by thirty three (9.7 percent) and unsuccessful treatment outcomes was slightly increased to five (3.3 percent) respectively. Moreover, residence of patients, types of TB, nutritional status, smear result, follow up status and missed doses was variables showed baseline difference in TB notification between pre and era of COVID-19 period. There was no difference in TB treatment outcome between pre and era of COVID-19.

7.2. RECOMMENDATION

The following recommendations are made based on the finding of the present study:

For Shashamanne specialized hospital and health office

- Continuous strengthening notification of TB through active case finding.
- Increasing follow up among patients started treatment to maintain successful treatment outcomes at WHO standard level.
- Preventing medication missing through proper follow up during DOTS and continuation phase.

For Ministry of Health

- An emergency response mechanism should be established, including increased human resources, active case finding activities and household contact management.

For researchers

- Further studies should be done with large sample size by prospective study design in orde r to generalize on the long-term impact of the pandemic in general population.
- Searching and implementation of video or mobile based TB management like ‘telehealth’ and observational therapy in the future.

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ANNEXES: DATA COLLECTION CHECKLIST

Jimma University

Institute of Health sciences

Dear,

This structured data collecting checklist is prepared to collect data from patient charts on '' ***the effect of COVID-19 pandemic on the management of tuberculosis at Shashamanne comprehensive specialized hospital".***

This study is conducted as part of my MSc thesis in clinical pharmacy in collaboration with Jimma University School of graduate studies. The aim of the study is to assess the effect of COVID-19 pandemic on the management of TB during the era of COVID 19 among patient with TB at Shashamanne specialized hospital. The finding of this study will be help in identifying and addressing the gap seen in terms of tuberculosis diagnosis and treatment outcomes before and during COVID-19 pandemic at the hospital. You should keep information extracted from patients' medical record confidentially and not exposed to other parties.

Data collector

Name…….

Sign……

Instruction

A. Select your answer for the questions by marking "√" in the box provided

B. on instruction 'A' if your answer is out of the choice provided; write it in the space provided

C. for question with (-----) sign provided write answer accordingly on the space given

Section one: Socio demographic data of patients

S/NO	Demographic characteristics	Possible interventions
1	TB unique number	
2	Sex	Male □ Female □
3	Age	Children (</=15) □ adult (>15) □

4	Residence	Urban □ Rural □
5	Year of TB registration (date, month and year)	
6	Numbers of family contacted registered	<2□ 2-4□ ≥5□
7	Mode of linkage:	PHF □ PPM □

Section Two: clinical characteristics of patients

S/NO	Clinical condition	Possible intervention
1	Patient tested for HIV	Yes □ no □
1.1	If answer for question number 2 is yes':	positive □ negative □ unknown □
2	Nutritional status '	SAM□ MAM □ Normal□ unknown □
3	TB case notification pattern:	Clinical □ sputum microscopy (AFB)□ gene expert □ X ray □ ultrasound □ culture/ FNAC □
4	Type of TB identified:	Presumptive PTB □ Bacteriological confirmed PTB □ EPTB □
5	Category of patient:	New □ Relapse □ Treatment after failure □ Treatment after lost to follow up □ Transfer in □ Other □
6	Era of TB notification	Pre COVID-19 □ era of COVID-19 □

Section three: Treatment approach and follow up status

S/N	Treatment approach	Possible interventions

1	Which medicines patient had taken through his/her treatment?	2 RHZE/ 4RH □ 2RHE/ 7 RH □ 6RHZE □ 2 HRZ/4HR □ 2SERH/6(RH) □ 9(RH)E □ 2SEH/10(EH) □ 2RHZ+E/ 4RH
2	Does intensive phase for presumptive and bacteriological confirmed PTB patients finished properly?	YES □ NO □
3	Does appointment in continuation phase for presumptive and bacteriological confirmed PTB patients finished properly?	YES □ NO □
4	Does patient had any documented missed doses at TB clinic during follow up?	YES □ NO □,
5	Does patient develop any ADR related to anti TB drugs	YES □ NO □,
6	For pulmonary positive TB patients does sputum examination done on the 2 month of DOTS treatment	Positive □ Negative □ Not tested □
6.1	sputum examination on 5th month during treatment	Positive □ Negative □ Not tested □
6.2	sputum exam after full treatment	Positive □ Negative □ Not tested □
7	Does EPTB confirmed patients finished DOTs treatment properly?	YES □ NO □,

7.1	Does EPTB confirmed patients finished continuation phase properly?	YES □ NO □,
8	Nutritional status at end of 2nd, 5th and after full treatment respectively	SAM□ MAM □ Normal□ unknown □

Section four: Treatment outcome: If patient finished treatment, tick the following

S/N	Status of outcomes	
1	Cured	□
2	Completed	□
3	Lost to follow up	□
4	Died	□
5	Failed treatment	□
6	Moved to MDR-TB	□